

18-971-0 PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:

HIDENORI OHKI ET AL

SERIAL NO. 08/809,723

FILED: MAY 21, 1997



EXAMINER: MARSHALL

: GROUP ART UNIT: 1654

FOR: CYCLIC HEXAPEPTIDES HAVING
ANTIBIOTIC ACTIVITY

DECLARATION UNDER 37 C.F.R. §1.132

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

Now comes Mr. HIDENORI OHKI, who deposes and states:

1. That I am a graduate of Hiroshima University, Faculty of Science, and received a Master of Science degree in the year 1988.
2. From 1988 to the present, I have been employed by the Fujisawa Pharmaceutical Co., Ltd., Osaka, Japan, as an organic chemist, and I am now a Senior Research Chemist of the Medicinal Chemistry Research Laboratories.
3. That the following observations and experiments were made and carried out by me or under my direct supervision and control.

Data on the compound of Example 25 is provided below. The compound was assayed in the same manner as described in page 43 of the specification (with regard to Example 17), as follows:

Test 1 (Antimicrobial activity):

In vitro antimicrobial activity of the compound of Example 25 was determined by the two-fold agar-plate dilution method as described below.

Test Method

One loopful of an overnight culture of each test microorganism in Sabouraud broth containing 2% Glucose (10^5 viable cells per ml) was streaked on yeast nitrogen base dextrose agar (YNBDA) containing graded concentrations of the compound of Example 25, and the minimal inhibitory concentration (MIC) was expressed in terms of $\mu\text{g/ml}$ after incubation at 30°C for 24 hours.

Test Results

Test organism	The compound of Example 25
<i>candida albicans</i> FP-633	MIC = 0.05 $\mu\text{g/ml}$

This result along with data in my previous declaration under 37 CFR 1.132 shows that the polypeptide compounds (I) of the present invention, as amended, have excellent antimicrobial activity, especially antifungal activity.

4. The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under

Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

5. Further deponent sayeth not.

Hidenori Ohki
Name

Signature

Date

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